DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 6 2012

Re: TEFLARO
Patent Nos. 6,417,175 and 6,906,055
Docket Nos.: FDA-2011-E-0245
and FDA-2011-E-0246

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,417,175 and 6,906,055, filed by Takeda Pharmaceutical Company Limited, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for TEFLARO (ceftaroline fosamil), the human drug product claimed by the patents.

The total length of the regulatory review period for TEFLARO (ceftaroline fosamil) is 2,118 days. Of this time, 1,814 days occurred during the testing phase and 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 12, 2005.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 12, 2005.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 30, 2009.

   FDA has verified the applicant's claim that the new drug application (NDA) for TEFLARO (NDA 200-327) was submitted on December 30, 2009.

3. The date the application was approved: October 29, 2010.

   FDA has verified the applicant's claim that NDA 200-327 was approved on October 29, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Stephen B. Maebius
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